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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,014	07/31/2003	Christopher J. Calhoun	MA9606P	9368
<div>7590 08/22/2007 Stout, Uxa, Buyan & Mullins, LLP Suite 300 4 Venture Irvine, CA 92618</div>			<div>EXAMINER SOROUSH, ALI</div>	
			<div>ART UNIT 1616</div>	<div>PAPER NUMBER</div>
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/632,014

Applicant(s)

CALHOUN ET AL.

Examiner

Ali Soroush

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29,34-36 and 51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-29,34-36 and 51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Acknowledgement of Receipt

Applicant's response filed on 05/17/2007 to Office Action mailed on 04/02/2007 is acknowledged.

Status of Claims

Claims 37 –50 have been cancelled, claims 1, 8, 34 and 38 have been amended, and claim 51 has been newly added.

Claim Rejections - 35 USC § 102

1. Claims 1, 2, 4, 5, 14-17, 21, 22, amended claims 34-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Arm et al. (WO 93/20859, Published 10/28/1993).

Applicant argues that the rejection does not anticipate the instant methods because the Arm et al. teaches the use of carriers and growth factors. Applicant argues that the use of these components would render the polymer porous and further would encourage tissue growth rather than impede it. With regards to the carrier causing pores this is only one of three alternatives of the mode of action of the carrier. Arm et al. teaches **"any substance that enhances polymer degradation, creates pores or reduces adsorption of the growth factor(s) to the film ..."** (See page 11, Lines 22-24). Two of the three alternative modes of action, as highlighted in the quote, leave the polymer film intact or causes resorption of the polymer, that is it does not cause pore formation. This clearly implies that the polymer film is in fact non-porous when applied to the implant and only in one case are pores formed by the action of the carrier. With regards to the polymer comprising growth factor which would encourage tissue growth

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as apposed to impeded tissue growth applicant is directed to page 4 line 22 and page 5 lines 1-2 of the Office Action mailed on 04/02/2007 which discloses the teaching of Arm et al. of a polymer film consisting of 100% polylactic acid. It would be expected that a polymer coating that lacks growth factor would impede the adhesion of tissue to the implant. It is noted that applicant has argued that this film is taught by Arm et al to be inferior and not useful. However applicant is respectfully directed to MPEP 2123 which states: "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." In re Gurley, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994). With regards to Applicant's argument that "consisting essentially of" language would limit the polymer material to either lactide polymer or a copolymer of two or more cyclic esters, it is the examiner position that the broadest reasonable interpretation of the claims are that the polymer base material comprises lactide polymer or a copolymer of two or more cyclic esters. However the polymer is not limited to consisting of only said polymers as noted by the claim reciting "the resorbable thin membrane is substantially non-porous and **comprises** a layer of polymer base material". The consisting essentially of language is written in Markush language as recited in the claim "selected from the group consisting essentially of". The claim only limits which types of polymers can be used in the base material but not the components of the film. It is suggested by the examiner that if applicant wishes to limit the components of the film that the claim read "wherein the resorbable thin membrane is substantially non-porous and consists essentially of a lactide polymer or a copolymer of two or more cyclic esters". For the foregoing reasons

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the applicants arguments are not found to be persuasive and the rejection is **maintained**.

Claim Rejections - 35 USC § 103

1. Claims 1, 4, 7-18, 21, 22 are rejected under 35 U.S.C. as being unpatentable over Hosseiny et al. (US 6451373, Published 09/17/2002).

With regards to Applicant's argument that "consisting essentially of" language would limit the polymer material to either lactide polymer or a copolymer of two or more cyclic esters, it is the examiner position that the broadest reasonable interpretation of the claims are that the polymer base material comprises lactide polymer or a copolymer of two or more cyclic esters. However the polymer is not limited to consisting of only said polymers as noted by the claim reciting "the resorbable thin membrane is substantially non-porous and **comprises** a layer of polymer base material". The consisting of essentially language is written in Markush language as recited in the claim "selected from the group consisting essentially of". The claim only limits which types of polymers can be used in the base material but not the components of the film. It is suggested by the examiner that if applicant wishes to limit the components of the film that the claim read "wherein the resorbable thin membrane is substantially non-porous and consists essentially of a lactide polymer or a copolymer of two or more cyclic esters". For the foregoing reasons the applicants arguments are not found to be persuasive and the rejection is **maintained**.

2. Claims 1-6, and 21-29 are rejected under 35 U.S.C. as being unpatentable over Ledergerber et al. (US 4955907, Published 09/11/1990) in view of Calhoun et al.

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(US 2002/0001609 A1, Published 01/03/2002). Applicant has requested further clarification of the statements made in Office Action mailed 04/02/2007 in regards to common ownership of Calhoun et al. reference. In the previous Office Action it was stated: Examiner acknowledges that assignment is indeed the same however for a prior art reference to be excluded under 35 U.S.C. 103(c) the prior art date would have to fall under 35 U.S.C. 102(e), (f), or (g). However the examiner failed to point out that although the reference is commonly owned it is not considered to have the same inventive entity. The instant application cites Christopher Calhoun, Ralph Holmes, and G. Cornwall as the inventors. However the reference cites Christopher Calhoun and Ralph E. Holmes as the inventors, therefore the prior art has a 102(a) date. Under 35 U.S.C. 103(c) a reference that is commonly owned but has a different inventive entity and further has a priority date that falls under 35 U.S.C. 102(a) **can be used** as prior art. It is noted that the current reference has a priority date that falls under 35 U.S.C. 102(e) as well as 102 (a). For the foregoing reasons the applicants arguments are not found to be persuasive and the rejection **is maintained**.

3. Claims 1, 4, 7, 13-23, 25, 29, and amended claims 34-36 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Lahtinen (US 2003/0059463 A1, published 3/27/2003).

Applicant argues that Lahtinen lacks motivation to produce a polymer coating that is substantially porous and consists polylactic acid polymer or a copolymer of two or more cyclic esters. Applicants argument is not persuasive because Latinen does disclose that the polymer coating maybe porous or nonporous. Further, Latinen

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discloses that the polymer coating can be formulated from a variety of polymers that includes poly-lactic acid and poly(D,L-lactic acid). Applicant has not provided any unexpected results of their invention and since the prior art suggests a non-porous base material with the instant polymer it is the examiners position that the instant invention is obvious to a skilled artisan. For the foregoing reasons the applicants arguments are not found to be persuasive and the rejection **is maintained**.

New Grounds of Rejection

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

New Claim 51 is rejected under 35 U.S.C. 102(b) as being anticipated by Arm et al. (WO 93/20859, Published 10/28/1993).

Arm et al. teaches, "biodegradable films comprising a polylactic/polyglycolic acid copolymer, a therapeutically effective amount of polypeptide growth factor, and a carrier are provided." (See abstract). "Compositions are in the form of biodegradable polyester films, such as polylactic acid, polyglycolic acid ..." (See page 5, Lines 12-13). "Because polymers of enantiomeric lactides are crystalline and therefore more resistant to degradation than their racemic counterparts, it is preferred to used mixed enantiomer (e.g. poly (D, L-lactide acid)) polymers within the present invention." (See page 6, Lines

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19-23). "Film thickness of less than about 50 μm are preferred, particularly film thickness between 5 and 20 μm ." (See page 6, Lines 33-35). "The films may be affixed to the outer surface of an implantable or prosthetic device such as a screw, pin, plate, rod or artificial joint component." (See abstract). Arm et al. teaches the use of the film with non-biological implants such as a medical device, i.e. "rods" for "enhancing bone repair of bone fractures" (see abstract) and also with biological implants such as an allograft material, i.e. "demineralized bone matrix plugs" to induce new bone formation. "The films may, for example, be wrapped around the outer surfaces of surgical screws, rods, pins, plates, and the like. The films can also be used to coat bone filling materials, such as hydroxyapatite blocks, demineralized bone matrix plugs, collagen matrices and the like ..." (See page 13, Lines 9-19). In regards to resorbability of the film Arm et al. teaches, "the unloaded *in vitro* degradation study showed mass loss from 50:50 and 85:15 PLA/PGA copolymer rods in the range of 80-95% by the 76-day point ..." (See page 15, Lines 25-27). In regards to the film characteristic being nonporous although Arm et al. is silent to this because the film has the same characteristic composition therefore products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. Therefore, it is the examiners position that the film taught by Arm et al. would be nonporous for the reasons above. For the foregoing reasons the instant method is anticipated.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ali Soroush whose telephone number is (571) 272-9925. The examiner can normally be reached on Monday through Thursday 8:30am to 5:00pm E.S.T.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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